

WHAT IS CLAIMED IS:

1 1. A luminal prosthesis comprising:
2 a scaffold which is implantable within a body lumen; and
3 means on the scaffold for releasing a substance, wherein the substance is
4 released over a predetermined time pattern comprising an initial phase wherein a substance
5 delivery rate is below a threshold level and a subsequent phase wherein the substance
6 delivery rate is above a threshold level.

1 2. A luminal prosthesis as in claim 1, wherein the scaffold is a stent or
2 graft.

1 3. A luminal prosthesis as in claim 1, wherein the scaffold is implantable
2 in a blood vessel.

1 4. A luminal prosthesis as in claim 1, wherein the means for releasing the
2 substance comprises a matrix formed over at least a portion of the scaffold.

1 5. A luminal prosthesis as in claim 4, wherein the matrix is composed of
2 a material which undergoes degradation in a vascular environment.

1 6. A luminal prosthesis as in claim 5, wherein the matrix degrades by
2 surface degradation.

1 7. A luminal prosthesis as in claim 5, wherein the matrix degrades by
2 bulk degradation.

1 8. An improved method for delivering a pharmacological agent to an
2 artery, said method being of the type where a prosthesis is implanted within the artery and the
3 prosthesis releases the pharmacological agent, wherein the improvement comprises
4 implanting a prosthesis that is programmed to begin substantial release of the
5 pharmacological agent beginning after growth of at least one layer of cells over a part of the
6 prosthesis.

1 9. A method as in Claim 8, wherein the cells comprise inflammatory,
2 smooth muscle, or endothelial cells.

1 10. A method for luminal substance delivery, said method comprising:

2 providing a luminal prosthesis incorporating or coupled to the substance,
3 wherein the prosthesis contains a matrix which undergoes degradation in a vascular
4 environment; and

5 implanting the prosthesis in a body lumen so that at least a portion of the
6 matrix degrades over a predetermined time period and substantial substance release begins
7 after the matrix substantially begins to degrade.

1 11. A method as in Claim 10, wherein the substance is incorporated in a
2 reservoir in or on a scaffold and the reservoir is covered by the matrix so that substantial
3 substance release begins after the matrix has degraded sufficiently to uncover the reservoir.

1 12. A method as in Claim 10, wherein the substance is contained in the
2 matrix and the matrix coats a scaffold, wherein an outer layer of the matrix is substantially
3 free from the substance so that substance release will not substantially begin until the outer
4 layer has degraded.

1 13. A method as in Claim 10, wherein the substance is contained within or
2 on a scaffold coated by the matrix.

1 14. A method as in Claim 10, wherein the prosthesis is coated with the
2 matrix by spraying, dipping, deposition, or painting.

1 15. A method as in Claim 10, wherein the prosthesis incorporates the
2 substance by coating, spraying, dipping, deposition, or painting the substance on the
3 prosthesis.

1 16. A method for treatment of a patient, comprising:
2 providing a vascular prosthesis comprising a structure and at least one source
3 of at least one therapeutic capable agent associated with the structure;
4 implanting the vascular prosthesis within the patient's vasculature including a
5 susceptible tissue site;
6 releasing at least one therapeutic capable agent.

1 17. The method of Claim 16 wherein releasing comprises releasing at least
2 one therapeutic capable agent is selected from the group consisting of immunosuppressants,
3 anti-inflammatories, anti-proliferatives, anti-migratory agents, anti-fibrotic agents,

proapoptotics, calcium channel blockers, anti-neoplastics, antibodies, anti-thrombotic agents, anti-platelet agents, IIb/IIIa agents, antiviral agents, and a combination thereof.

18. The method of Claim 16 wherein releasing comprises releasing at least one therapeutic capable agent is selected from the group consisting of mycophenolic acid, mycophenolate mofetil, mizoribine, methylprednisolone, dexamethasone, Certican™, rapamycin, Triptolide™, Methotrexate™, Benidipine™, Ascomycin™, Wortmannin™, LY294002, Camptothecin™, Topotecan™, hydroxyurea, Tacrolimus™ (FK 506), cyclophosphamide, cyclosporine, daclizumab, azathioprine, prednisone, Gemcitabine™, derivatives and combinations thereof.

19. The method of Claim 16 further comprising reducing smooth muscle cell proliferation at the susceptible tissue site.

20. The method of Claim 16 wherein therapeutic capable agent is released within a time period of about 1 day to about 200 days from the implanting of the prosthesis.

21. The method of Claim 16 wherein therapeutic capable agent is released within a time period of about 1 day to about 45 days from the implanting of the prosthesis.

22. The method of Claim 20 wherein therapeutic capable agent is released within a time period of about 7 days to about 21 days from the implanting of the prosthesis.

23. The method of Claim 16 further comprising releasing at least another compound.

24. The method of Claim 23 wherein the another compound is another therapeutic capable agent.

25. The method of Claim 23 wherein the releasing comprising releasing another compound selected from the group consisting of anti-cancer agents; chemotherapeutic agents; thrombolytics; vasodilators; antimicrobials or antibiotics; antimitotics; growth factor antagonists; free radical scavengers; biologic agents; radiotherapeutic agents; radiopaque agents; radiolabelled agents; anti-coagulants such as heparin and its derivatives; anti-angiogenesis drugs; angiogenesis drugs; PDGF-B and/or EGF inhibitors; anti-inflammatories including psoriasis drugs; anti-platelet agents including, cyclooxygenase inhibitors such as acetylsalicylic acid, ADP inhibitors ticlopidine

phosphodiesterase III inhibitors, glycoprotein IIb/IIIa agents; eptifibatides, and adenosine reuptake inhibitors; healing and/or promoting agents including anti-oxidants, nitrogen oxide donors; antiemetics; antinauseants; derivatives and combinations thereof.

26. The method of Claim 23 wherein the releasing comprises releasing another compound selected from the group consisting of heparin and its derivatives; Thalidomide™; riboflavin; tiazofurin; zafurin; acetylsalicylic acid, clopidogrel such as Plavix™, ticlopidipine such as ticlid™, cilostazol such as Pletal™, abciximab such as Rheopro™; eptifibatide such as Integrilin™, dipyridmoles; NSAID, Taxol™, Actinomycine DTM; derivatives and combinations thereof.

27. The method of Claim 23 wherein the another compound is an enabling compound.

28. The method of Claim 23 wherein the another compound is released prior to the therapeutic capable agent.

29. The method of Claim 23, 24, 25, 26, or 27 wherein the another compound is released concurrent with the therapeutic capable agent.

30. The method of Claim 23, 24, 25, 26, or 27 wherein the another compound is released sequentially with the therapeutic capable agent.

31. The method of Claim 16 wherein the device is configured to release the therapeutic capable agent at a total amount ranging from about 0.1 ug to about 10 g.

32. The method of Claim 16 wherein the therapeutic capable agent is released at a total amount ranging from about 0.1 ug to about 10 mg.

33. The method of Claim 16 wherein the therapeutic capable agent is released at a total amount ranging from about 1 ug to about 2 mg.

34. The method of Claim 16 wherein the therapeutic capable agent is released at a total amount ranging from about 1 ug to about 10 mg.

35. The method of Claim 16 wherein the therapeutic capable agent is released at a total amount ranging from about 10 ug to about 2 mg.

36. The method of Claim 16 wherein the therapeutic capable agent is released at a total amount ranging from about 50 ug to about 1 mg.

37. The method of Claim 16 further comprising administering a second compound to the patient independent of that provided with the device.

38. The method of Claim 37 wherein the second compound is selected from the group consisting of compounds according to any of Claims 2, 3, 10, 11, and combinations thereof.

39. The method of Claim 38 wherein the second compound is selected from the group consisting of ondansetron such as Zofran™, dronabinol such as Marinol™, ganisetron.Hcl such as Kytril™, and combinations thereof.

40. The method of Claim 37, 38, or 39 wherein administering the second compound comprises orally, pulmonarily, systemically, transdermally, through any bodily orifice, or any one or more combinations thereof.

41. The method of Claim 40 wherein the administering the second compound comprises administering prior to, concurrent with, or subsequent to, the interventional procedure.

42. The method of Claim 40 wherein the administering the second compound comprises administering to the patient in a time period from about 200 days prior to about 200 days after the interventional procedure.

43. The method of Claim 40 wherein the administering the second compound comprises administering to the patient in a time period from about 30 days prior to about 30 days after the interventional procedure.

44. The method of Claim 40 wherein the administering the second compound comprises administering to the patient in a time period from about 1 day prior to about 30 days after the interventional procedure.

45. The method of Claim 40 wherein the administering the second compound comprises administering to the patient in a time period from about 200 days prior to about up to the interventional procedure.

1 46. The method of Claim 40 wherein the administering the second
2 compound comprises administering to the patient in a time period from about 3 months prior
3 to about up to the interventional procedure.

1 47. The method of Claim 40 wherein the administering the second
2 compound comprises administering to the patient in a time period from about 7 days to about
3 24 hours prior to the interventional procedure.

1 48. The method of Claim 40 wherein the administering the second
2 compound comprises administering an acute dose ranging from about 0.5 mg to about 5 g.

1 49. The method of Claim 40 wherein the administering the second
2 compound comprises administering an acute dose ranging from about 1 mg to about 3 g.

1 50. The method of Claim 40 wherein the administering the second
2 compound comprises administering an acute dose ranging from about 1 g to about 1.5 g.

1 51. The method of Claim 40 wherein the administering the second
2 compound comprises administering an acute dose ranging from about 2 g to about 3 g.

1 52. The method of Claim 40 wherein the administering the second
2 compound comprises administering a dose per day ranging from about 1 g to about 1.5 g.

1 53. The method of Claim 40 wherein the administering the second
2 compound comprises administering a dose per day ranging from about 1 mg to about 3 mg.

1 54. The method of Claim 40 wherein the administering the second
2 compound comprises administering a dose per day ranging from about 2 g to about 3 g.

1 55. The method of Claim 40 wherein the administering the second
2 compound comprises administering a dose per day ranging from about 2 mg to about 6 mg.

1 56. A method for delivering a therapeutic capable agent to a susceptible
2 tissue site within a corporeal body, comprising:
3 positioning a source of the therapeutic capable agent within a vascular lumen;
4 releasing the therapeutic capable agent to the susceptible tissue site.

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1 67. The method of Claim 66 wherein the device is positioned within the
2 corporeal body during a vascular intervention.

1 68. The method of Claim 67 wherein the release of the therapeutic capable
2 agent is delayed for a predetermined period of time following the positioning of the device
3 within the corporeal body.

1 69. The method of Claim 68 wherein the delay is sufficiently long to allow
2 sufficient generation of intimal tissue to reduce occurrence of thrombotic event.

1 70. The method of Claim 63 or 64 wherein the corporeal body is a body
2 lumen.

1 71. The method of Claim 63 or 64 wherein the corporeal body is an organ.

1 72. The method of Claim 63 or 64 further including directing energy at the
2 device to effect release of the therapeutic capable agent from the device.

1 73. The method of Claim 72 wherein the energy is at least one of
2 ultrasound, magnetic resonance imaging, magnetic field, radio frequency, temperature
3 change, electromagnetic, x-ray, heat, vibration, gamma radiation, microwave, or a
4 combination thereof.

1 74. A device for intracorporeal use, comprising:
2 a structure; and
3 at least one source of at least one therapeutic capable agent associated with
4 the structure.

1 75. The device of Claim 74 wherein the source is configured to provide the
2 at least one therapeutic capable agent to a targeted intracorporeal site within an intracorporeal
3 body.

1 76. The device of Claim 75 wherein the targeted intracorporeal site
2 comprises a body lumen.

1 77. The device of Claim 75 wherein the targeted intracorporeal site
2 comprises a body organ.

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- 1 78. The device of Claim 75 wherein the device is configured for
2 implanting at the targeted intracorporeal site supplying blood to a susceptible tissue site.
- 1 79. The device of Claim 75 wherein the targeted intracorporeal site
2 includes a susceptible tissue site.
- 1 80. The device of Claim 75 or 76 wherein the device comprises a vascular
2 prosthesis.
- 1 81. The device of Claim 80 wherein the vascular prosthesis comprises an
2 expandable structure.
- 1 82. The device of Claim 81 wherein the vascular prosthesis comprises a
2 graft.
- 1 83. The device of Claim 81 wherein the vascular prosthesis comprises a
2 stent.
- 1 84. The device of Claim 83 wherein prosthesis comprises a scaffold
2 formed at least in part from an open lattice.
- 1 85. The device of Claim 75 wherein source is the therapeutic capable
2 agent.
- 1 86. The device of Claim 81 wherein the expandable structure has a luminal
2 and a tissue facing surface.
- 1 87. The device of Claim 86 wherein the therapeutic capable agent is
2 associated with the expandable structure on at least one of the expandable structure luminal
3 or tissue facing surfaces.
- 1 88. The device of Claim 86 wherein the expandable structure has an
2 interior.
- 1 89. The device of Claim 88 wherein therapeutic capable agent is associated
2 with the interior of the expandable structure.

1 90. The device of Claim 75 or 87 wherein the expandable structure is
2 formed from an at least partially degradable material.

1 91. The device of Claim 90 wherein the at least partially degradable
2 material is at least partially biodegradable.

1 92. The device of Claim 90 wherein the at least partially biodegradable
2 material comprises a metal or alloy degradable in the corporeal body.

1 93. The device of Claim 92 wherein the metal or alloy alloy comprises
2 stainless steel.

1 94. The device of Claim 93 wherein the therapeutic capable agent is made
2 available to the susceptible tissue site as the stainless steel degrades within the corporal body
3 over time.

1 95. The device of Claim 85 wherein the therapeutic capable agent
2 comprises a polymeric material formed at least in part from therapeutic capable agent.

1 96. The device of Claim 95 wherein the therapeutic capable agent units are
2 disassociated in the corporeal body.

1 97. The device of Claim 95 wherein the therapeutic capable agent units are
2 disassociated in a vascular environment.

1 98. The device of Claim 95 wherein the therapeutic capable agent units are
2 disassociated over time.

1 99. The device of Claim 85 wherein the source is a polymeric material
2 including the therapeutic capable units associated with a polymeric backbone.

1 100. The device of Claim 85 wherein the source is a polymeric material
2 including the therapeutic capable units associated with a metallic backbone.

1 101. The device of Claim 74 wherein the device is configured to release the
2 therapeutic capable at release rate.

102. The device of Claim 101 wherein the rate provides a sustainable level of therapeutic capable agent to the susceptible tissue site.

103. The device of Claim 101 wherein the rate is substantially constant.

104. The device of Claim 101 wherein the rate decreases over time.

105. The device of Claim 101 wherein the rate increases over time.

106. The device of Claim 101 wherein the rate includes a substantially non-release period.

107. The device of Claim 101 wherein the release rate is pre-defined.

108. The device of Claim 101 wherein the release rate includes a plurality of rates.

109. The device of Claim 108 wherein the plurality of rates includes at least two rates selected from the group consisting of substantially constant, decreasing, increasing, substantially non-releasing.

110. The device of Claim 87 wherein the source is disposed adjacent at least one of the luminal or tissue facing surfaces of the expandable structure.

111. The device of Claim 110 wherein the source comprises a matrix including the therapeutic capable agent.

112. The device of Claim 75 or 81 further including a rate-controlling element.

113. The device of Claim 112 wherein the source comprises the rate-controlling element.

114. The device of Claim 112 wherein the rate-controlling element is disposed adjacent at least a portion of the source.

115. The device of Claim 114 wherein at a least a portion of the rate-controlling element forms a matrix with the therapeutic capable agent.

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1 116. The device of Claim 114 wherein the rate-controlling element forms
2 the outer most layer of the device.

1 117. The device of Claim 112 wherein the rate-controlling element is
2 disposed adjacent at least a portion of the expandable structure.

1 118. The device of Claim 112, 113, 114, 116, or 117 wherein the rate-
2 controlling element is formed from a material selected from the group consisting of
3 polymeric, metallics, bioactive compounds, and non-bioactive compounds.

1 119. The device of Claim 118 wherein the rate-controlling element material
2 comprises a polymeric material.

1 120. The device of Claim 119 further comprising a second rate-controlling
2 element disposed adjacent at least a portion of the first rate-controlling element.

1 121. The device of Claim 118 wherein the rate-controlling element is
2 formed from a biodegradable material.

1 122. The device of Claim 118 wherein the rate-controlling element is
2 formed from a material selected from the group consisting of poly(lactic acid), poly(glycolic
3 acid) and copolymers, poly dioxanone, poly (ethyl glutamate), poly (hydroxybutyrate),
4 polyhydroxyvalerate and copolymers, polycaprolactone, polyanhydride, poly(ortho esters);
5 poly (iminocarbonates), polycyanoacrylates, polyphosphazenes, copolymers and other
6 aliphatic polyesters, or suitable copolymers thereof including copolymers of poly-L-lactic
7 acid and poly-D-caprolactone; mixtures, copolymers, and combinations thereof.

1 123. The device of Claim 121 wherein the therapeutic capable agent is
2 released by surface degradation or hydrolysis of the rate-controlling element.

1 124. The device of Claim 121 wherein the therapeutic capable agent is
2 released by bulk degradation of the rate-controlling element.

1 125. The device of Claim 118 wherein the rate-controlling element is
2 formed from a non-biodegradable or slow degrading material.

1 126. The device of Claim 118 wherein the rate-controlling element is
2 formed from a material selected from the group consisting of polyurethane, polyethylenes
3 imine, cellulose acetate butyrate, ethylene vinyl alcohol copolymer, silicone,
4 polytetrafluoroethylene (PTFE), parylene, parylast, poly (methyl methacrylate butyrate), poly-
5 N-butyl methacrylate, poly (methyl methacrylate), poly 2-hydroxy ethyl methacrylate, poly
6 ethylene glycol methacrylates, poly vinyl chloride, poly(dimethyl siloxane),
7 poly(tetrafluoroethylene), poly (ethylene oxide), poly ethylene vinyl acetate, poly carbonate,
8 poly acrylamide gels, N-vinyl-2-pyrrolidone, maleic anhydride, Nylon, cellulose acetate
9 butyrate (CAB) and the like, including other synthetic or natural polymeric substances;
10 mixtures, copolymers, and combinations thereof.

1 127. The device of Claim 118 wherein the rate-controlling element is
2 formed from a material selected from the group consisting of silicone,
3 polytetrafluoroethylene, parylast, polyurethane, parylene, cellulose acetate butyrate; mixtures,
4 copolymers and combinations thereof.

1 128. The device of Claim 118 wherein the rate-controlling element is
2 formed from a natural material.

1 129. The device of Claim 118 wherein the rate-controlling element is
2 formed from a material selected from the group consisting of fibrin, albumin, collagen,
3 gelatin, glycosoaminoglycans, chondroitin, oligosaccharides & poly saccharides,
4 phosholipids, phosphorylcholine, glycolipids, proteins, amino acids, cellulose, and mixtures,
5 copolymers, or combinations thereof.

1 130. The device of Claim 125 wherein the therapeutic capable agent is
2 released by diffusion through the rate-controlling element.

1 131. The device of Claim 118 wherein the rate-controlling element
2 comprises a metallic material.

1 132. The device of Claim 118 wherein the rate-controlling element is
2 formed from a material selected from the group consisting titanium, chromium, Nitinol, gold,
3 stainless steel, alloys, and combinations thereof.

1 133. The device of Claim 132 wherein the metals or alloys are at least two
2 and having different galvanic potential.

1 134. The device of Claim 118 wherein the rate-controlling element includes
2 a plurality of layers.

1 135. The device of Claim 134 wherein at least one of the rate-controlling
2 element plurality of layers includes the therapeutic capable agent.

1 136. The device of Claim 135 wherein the layers other than the at least one
2 layer includes the same or a different therapeutic capable agent.

1 137. The device of Claim 86 wherein the source is a reservoir disposed
2 adjacent the expandable structure.

1 138. The device of Claim 137 wherein the reservoir is at least partially on
2 an exterior of the expandable structure.

1 139. The device of Claim 137 wherein the reservoir is at least partially in
2 the interior of the expandable structure.

1 140. The device of Claim 137 wherein the reservoir is at least partially on
2 either or both the luminal and the tissue facing surfaces of the expandable structure.

1 141. The device of Claim 137 wherein the reservoir is at least partially in
2 the expandable structure.

1 142. The device of Claim 138 or 139 wherein a rate-controlling element is
2 disposed at least partially adjacent the reservoir.

1 143. The device of Claim 140 or 141 wherein a rate-controlling element is
2 disposed at least partially over the reservoir.

1 144. The device of 113 or 115 wherein the rate-controlling element has
2 thickness ranging from about 10 nm to about 100 um.

1 145. The device of Claim 144 wherein the rate-controlling element has
2 thickness ranging from about 50 nm to about 100 um.

1 146. The device of Claim 144 wherein the rate-controlling element has
2 thickness ranging from about 100 nm to about 50 um.

1 147. The device of Claim 144 wherein the rate-controlling element has
2 thickness ranging from about 100 nm to about 10 um.

1 148. The device of Claim 144 wherein the device further comprises a bio-
2 compatible outer layer.

1 149. The device of Claim 148 wherein the bio-compatible layer is formed
2 from a material consisting of polyethylene glycol, polyethylene oxide, hydrogels, silicone,
3 polyurethanes, heparin, and combinations thereof.

1 150. A device for intracorporeal use, comprising:
2 an expandable member having at least one of luminal and tissue facing
3 surfaces; and
4 at lease one source of at least one therapeutic capable agent disposed adjacent
5 at least one of the luminal or tissue facing surfaces.

1 151. The device of Claim 150 wherein the therapeutic capable agent
2 comprises at least one agent selected from the group consisting of immunosuppressants, anti-
3 inflammatories, anti-proliferatives, anti-migratory agents, anti-fibrotic agents, proapoptotics,
4 calcium channel blockers, anti-neoplastics, antibodies, anti-thrombotic agents, anti-platelet
5 agents, IIb/IIIa agents, antiviral agents, and a combination thereof.

1 152. The device of Claim 151 wherein the therapeutic capable agent has
2 more than one therapeutic effect.

1 153. The device of Claim 152 wherein the therapeutic capable agent has
2 anti-inflammatory and immunosuppressant effects.

1 154. The device of Claim 152 wherein the therapeutic capable agent has
2 anti-inflammatory and anti-proliferative effects.

1 155. The device of Claim 152 wherein the therapeutic capable agent has
2 immunosuppressants and anti-proliferative effects.

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1 163. The device of Claim 159 wherein the another compound is selected
2 from the group consisting of heparin and its derivatives; Thalidomide™; riboflavin;
3 tiazofurin; zafurin; acetylsalicylic acid, clopidogrel such as Plavix™, ticlopidipine such as
4 ticlid™, cilostazol such as Pletal™, abciximab such as Rheopro™; eptifibatide such as
5 Integrilin™, dipyridmoles; NSAID, Taxol™, Actinomycine DTM; derivatives and
6 combinations thereof.

1 164. The device of Claim 159 wherein the another compound is selected
2 from the group consisting of NSAID, Taxol™, Actinomycine DTM.

1 165. The device of Claim 159 wherein the another compound is a magnetic
2 particle.

1 166. The device of Claim 151, 157, 158, or 161 wherein the device is
2 configured to release the therapeutic capable agent in response to an external source of
3 energy.

1 167. The device of Claim 166 wherein the external source of energy is
2 ultrasound, magnetic resonance imaging, magnetic field, radio frequency, temperature
3 change, electromagnetic, x-ray, heat, vibration, gamma radiation, microwave, or a
4 combination thereof.

1 168. The device of Claim 166 wherein the external source of energy is a
2 magnetic field.

1 169. The device of Claim 159 wherein the device is configured to release
2 the another compound prior to, concurrent with, or subsequent to the release of the
3 therapeutic capable agent.

1 170. The device of Claim 150, 157, or 158 wherein the device is configured
2 to release the therapeutic capable agent in an intracorporeal body.

1 171. The device of Claim 170 wherein the device is configured to release
2 the therapeutic capable agent at a rate between about 0.001 ug to about 200 ug/day.

1 172. The device of Claim 170 wherein the device is configured to release
2 the therapeutic capable agent at a rate between about 0.5 ug to about 200 ug/day.

1 173. The device of Claim 170 wherein the device is configured to release
2 the therapeutic capable agent at a rate between about 1 ug to about 100 ug/day.

1 174. The device of Claim 170 wherein the device is configured to release
2 the therapeutic capable agent at a rate between about 10 ug to about 60 ug/day.

1 175. The device of Claim 170 wherein the device is configured to release
2 the therapeutic capable agent at a rate between about 1 ug to about 60 ug/day.

1 176. The device of Claim 170 wherein the device is configured to release
2 the therapeutic capable agent at different phases.

1 177. The device of Claim 176 wherein the device is configured to release
2 the therapeutic capable agent at an initial phase having a lower rate of release than a
3 subsequent phase.

1 178. The device of Claim 176 wherein the device is configured to release
2 the therapeutic capable agent at an initial phase having a higher rate of release than a
3 subsequent phase.

1 179. The device of Claim 177 wherein the device is configured to release
2 the therapeutic capable agent at an initial phase having an initial rate of release ranging from
3 about 0 to about 99% of a subsequent rate of release of a subsequent phase.

1 180. The device of Claim 177 wherein the device is configured to release
2 the therapeutic capable agent at an initial phase having an initial rate of release ranging from
3 about 0 to about 90% of a subsequent rate of release of a subsequent phase.

1 181. The device of Claim 177 wherein the device is configured to release
2 the therapeutic capable agent at an initial phase having an initial rate of release ranging from
3 about 0 to about 75% of a subsequent rate of release of a subsequent phase.

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1 182. The device of Claim 177 wherein the device is configured to release
2 the therapeutic capable agent at an initial phase having an initial rate of release ranging from
3 about 0 to about 50% of a subsequent rate of release of a subsequent phase.

1 183. The device of Claim 177 wherein the device is configured to release
2 the therapeutic capable agent at an initial phase having an initial rate of release ranging from
3 about 0 to about 50 ug/day, and a subsequent phase having a subsequent rate of release
4 ranging from about 0.01 ug to about 200 ug/day.

1 184. The device of Claim 177 wherein the device is configured to release
2 the therapeutic capable agent at an initial phase having an initial rate of release ranging from
3 about 0.001 to about 50 ug/day, and a subsequent phase having a subsequent rate of release
4 ranging from about 0.01 ug to about 200 ug/day.

1 185. The device of Claim 177 wherein the device is configured to release
2 the therapeutic capable agent at an initial phase having an initial rate of release ranging from
3 about 0.1 to about 30 ug/day, and a subsequent phase having a subsequent rate of release
4 ranging from about 0.01 ug to about 200 ug/day.

1 186. The device of Claim 177 wherein the device is configured to release
2 the therapeutic capable agent at an initial phase having an initial rate of release ranging from
3 about 1 to about 20 ug/day, and a subsequent phase having a subsequent rate of release
4 ranging from about 0.01 ug to about 200 ug/day.

1 187. The device of Claim 177 wherein the device is configured to release
2 the therapeutic capable agent at an initial phase having an initial rate of release ranging from
3 about 0.1 to about 30 ug/day, and a subsequent phase having a subsequent rate of release
4 ranging from about 1.0 ug to about 100 ug/day.

1 188. The device of Claim 180 wherein the device is configured to release
2 the therapeutic capable agent at an initial phase having an initial rate of release ranging from
3 about 10 to about 300 ug/day, and a subsequent phase having a subsequent rate of release
4 ranging from about 0.1 to about 100 ug/day.

1 189. The device of Claim 178 wherein the device is configured to release
2 the therapeutic capable agent at an initial phase having an initial rate of release ranging from

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3 about 40 to about 300 ug/day, and a subsequent phase having a subsequent rate of release
4 ranging from about 0.5 to 40 ug/day.

1 190. The device of Claim 178 wherein the device is configured to release
2 the therapeutic capable agent at an initial phase having an initial rate of release ranging from
3 about 40 to about 200 ug/day, and a subsequent phase having a subsequent rate of release
4 ranging from about 10 to 40 ug/day.

1 191. The device of Claim 178 wherein the device is configured to release
2 the therapeutic capable agent at an initial phase having an initial rate of release ranging from
3 about 40 to about 200 ug/day, and a subsequent phase having a subsequent rate of release
4 ranging from about 0.5 to 40 ug/day.

1 192. The device of Claim 170 wherein the device is configured to release
2 the therapeutic capable agent at a substantially constant rate ranging from about 0.01 ug to
3 200 ug/day.

1 193. The device of Claim 170 wherein the device is configured to release
2 the therapeutic capable agent at a total amount ranging from about 0.1 ug to about 10 g.

1 194. The device of Claim 170 wherein the device is configured to release
2 the therapeutic capable agent at a total amount ranging from about 0.1 ug to about 10 mg.

1 195. The device of Claim 170 wherein the device is configured to release
2 the therapeutic capable agent at a total amount ranging from about 1 ug to about 2 mg.

1 196. The device of Claim 170 wherein the device is configured to release
2 the therapeutic capable agent at a total amount ranging from about 10 ug to about 2 mg.

1 197. The device of Claim 170 wherein the device is configured to release
2 the therapeutic capable agent at a total amount ranging from about 50 ug to about 1 mg.

1 198. The device of Claim 170 wherein the device is configured to deliver
2 the therapeutic capable agent at a phase to a susceptible tissue site of a mammalian
3 intracorporeal body to effectuate a mammalian tissue concentration ranging from about 0.001
4 ng of therapeutic capable agent / mg of tissue to about 100 ug of therapeutic capable agent /
5 mg of tissue.

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1 199. The device of Claim 170 wherein the device is configured to deliver
2 the therapeutic capable agent at a phase to a susceptible tissue site of a mammalian
3 intracorporeal body to effectuate a mammalian tissue concentration ranging from about 1 ng
4 of therapeutic capable agent / mg of tissue to about 100 ug of therapeutic capable agent / mg
5 of tissue.

1 200. The device of Claim 170 wherein the device is configured to deliver
2 the therapeutic capable agent at a phase to a susceptible tissue site of a mammalian
3 intracorporeal body to effectuate a mammalian tissue concentration ranging from about 1 ng
4 of therapeutic capable agent / mg of tissue to about 10 ug of therapeutic capable agent / mg of
5 tissue.

1 201. The device of Claim 158 wherein the device is configured to release
2 the therapeutic capable agent at a phase to a mammalian intracorporeal body to effectuate a
3 mammalian blood concentration ranging from about 1 ng of therapeutic capable agent / ml of
4 blood to about 50 ug of therapeutic capable agent / ml of blood.

1 202. The device of Claim 170 wherein the device is configured to release
2 the therapeutic capable agent at a phase to a mammalian intracorporeal body to effectuate a
3 mammalian blood concentration ranging from about 1 ng of therapeutic capable agent / ml of
4 blood to about 20 ug of therapeutic capable agent / ml of blood.

1 203. The device of Claim 170 wherein the device is configured to release
2 the therapeutic capable agent at a phase to a mammalian intracorporeal body to effectuate a
3 mammalian blood concentration ranging from about 2 ng of therapeutic capable agent / ml of
4 blood to about 12 ug of therapeutic capable agent / ml of blood.

1 204. The device of Claim 201, 202, or 203 wherein the phase is within the
2 first 24 hours after the implantation of the device in the mammalian intracorporeal body.

1 205. The device of Claim 201, 202, or 203 wherein the concentration is a
2 peak concentration.

1 206. The device of Claim 198 or 199 wherein the phase is a first phase.

1 207. The device of Claim 206 wherein the device is configured to deliver
2 the therapeutic capable agent at a second phase to the susceptible tissue site of the
3 mammalian intracorporeal body to effectuate a mammalian tissue concentration of the
4 therapeutic capable agent ranging from about 0.001 ng of therapeutic capable agent / mg of
5 tissue to about 100 ug of therapeutic capable agent / mg of tissue.

1 208. The device of Claim 207 wherein the tissue concentration ranges from
2 about 1 ng of therapeutic capable agent / mg of tissue to about 10 ug of therapeutic capable
3 agent /mg of tissue.

1 209. The device of Claim 170 wherein device is configured to release the
2 therapeutic capable agent at a substantially constant rate ranging from about 0.01 ug to 200
3 ug/day.

1 210. The device of Claim 176 wherein device is configured to deliver the
2 therapeutic capable agent at an initial and a subsequent phase.

1 211. The device of Claim 176 wherein at the initial phase the release of the
2 therapeutic capable agent is delayed.

1 212. The device of Claim 176, or 211 wherein the duration of the initial
2 phase is configured to last less than about 24 weeks.

1 213. The device of Claim 176, or 211 wherein the duration of the initial
2 phase is configured to last less than about 12 weeks.

1 214. The device of Claim 176, or 211 wherein the duration of the initial
2 phase is configured to last from about 1 hour to about 24 weeks.

1 215. The device of Claim 176, or 211 wherein the duration of the initial
2 phase is configured to last from about 1 hour to about 8 weeks.

1 216. The device of Claim 176, or 211 wherein the duration of the initial
2 phase is configured to last from about 12 hours to about 2 weeks.

1 217. The device of Claim 176, or 211 wherein the duration of the initial
2 phase is configured to last from about 1 day to about 1 week.

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- 1 218. The device of Claim 176, or 211 wherein the duration of the
2 subsequent phase is configured to last from about 4 hours to about 8 weeks.
- 1 219. The device of Claim 176, or 211 wherein the duration of the
2 subsequent phase is configured to last from about 1 hour to about 8 weeks.
- 1 220. The device of Claim 176, or 211 wherein the duration of the
2 subsequent phase is configured to last from about 1 hour to about 12 weeks.
- 1 221. The device of Claim 176, or 211 wherein the duration of the
2 subsequent phase is configured to last from about 1 hour to about 1 day.
- 1 222. The device of Claim 176 wherein the duration of the subsequent phase
2 is configured to last from about 1 day to about 12 weeks.
- 1 223. The device of Claim 176 wherein the duration of the subsequent phase
2 is configured to last from about 2 days to about 8 weeks.
- 1 224. The device of Claim 176 wherein the duration of the subsequent phase
2 is configured to last from about 3 days to about 50 weeks.
- 1 225. The device of Claim 176 wherein the duration of the subsequent phase
2 is configured to last from about 3 days to about 30 days.
- 1 226. The device of Claim 178 wherein the duration of the initial phase is
2 configured to last from about 1 day to about 7 days.
- 1 227. The device of Claim 178 wherein the duration of the initial phase is
2 configured to last from about 1 day to about 30 days.
- 1 228. The device of Claim 178 wherein the duration of the subsequent phase
2 is configured to last from about 2 days to about 45 days.
- 1 229. The device of Claim 226 wherein the device is configured to deliver
2 the therapeutic capable agent at the initial phase to a susceptible tissue site of a mammalian
3 intracorporal body to effectuate a mammalian tissue concentration of the therapeutic capable
4 agent ranging from about 10 ng / mg to about 100 ug / mg.

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1 230. The device of Claim 228 wherein the device is configured to deliver
2 the therapeutic capable agent at the initial phase to a susceptible tissue site of a mammalian
3 intracorporeal body to effectuate a mammalian tissue concentration of the therapeutic capable
4 agent ranging from about 10 ng / mg to about 100 ug / mg.

1 231. The device of Claim 170 wherein the device is configured to have a
2 termination phase delivering the therapeutic capable agent to a mammalian intracorporeal
3 body at a rate less than a rate of clearance the intracorporeal body of the therapeutic capable
4 agent.

1 232. The device of Claim 231 wherein the termination phase has a duration
2 of about 14 days.

1 233. The device of Claim 231 wherein the rate of clearance is about 1 ng to
2 about 100 ng per mg of tissue per day.

1 234. The device of Claim 231 wherein the rate of clearance is about 80 ng
2 per mg of tissue per day.

1 235. The device of Claim 231 wherein the rate of clearance is about 10 ng
2 per mg of tissue per day.

1 236. The device of Claim 150 wherein the source is associated with the
2 expandable structure by coating, spraying, dipping, vapor deposition, plasma deposition, or
3 painting of the source onto or in the expandable structure.

1 237. The device of Claim 236 wherein the source is mixed in a solvent
2 selected from the group consisting of methanol, DMSO, CO₂.

1 238. A device for intracorporeal use, comprising:
2 an expandable structure;
3 a source of therapeutic capable agent disposed adjacent the expandable
4 structure, and including a plurality of rate-controlling element layers at least one of which
5 comprises parylast or parylene, each layer having a thickness in a range from about 50 nm to
6 10 microns.

239. The device of Claim 238 wherein the expandable structure includes at least one of luminal or tissue facing surfaces.

240. The device of Claim 239 wherein the source is disposed adjacent either or both the at least one of luminal or tissue facing surfaces.

241. A device for intracorporeal use, comprising:
an expandable structure having luminal and tissue facing surfaces;
a source of therapeutic capable agent disposed adjacent at least one of the luminal or tissue facing surfaces; and
a rate-controlling element disposed adjacent the source.

242. The device of Claim 241 further comprising a matrix interface between the source and the rate-controlling element.

243. The device of Claim 241 wherein the source and the rate-controlling element form a matrix.

244. An intracorporeal device for delivering at least one therapeutic capable agents to a targeted area in a corporeal body, comprising:
an expandable;
a source of therapeutic capable agent disposed adjacent the expandable structure and configured to delay the release of the therapeutic capable.

245. The device of Claim 244 wherein the delay is sufficiently long to allow the formation of sufficient amount of cellularization at the susceptible tissue site.

246. The device of Claim 244 wherein the delay is sufficiently long to allow the formation of sufficient amount of cellularization on the device.

247. The device of Claim 244 wherein the delay is sufficiently long to allow the formation of sufficient amount of cellularization at the susceptible tissue site and on the device.

248. The device of Claim 244 wherein the delay is sufficiently long to allow the formation of sufficient amount of endothelization at the susceptible tissue site.

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1 249. The device of Claim 244 wherein the delay is sufficiently long to allow
2 the formation of sufficient amount of endothelialization on the device.

1 250. The device of Claim 244 wherein the delay is sufficiently long to allow
2 the formation of sufficient amount of endothelialization at the susceptible tissue site and on the
3 device.

1 251. The device of Claim 244 wherein the delay is sufficiently long to allow
2 the formation of sufficient amount of fibrin deposition at the susceptible tissue site.

1 252. The device of Claim 244 wherein the delay is sufficiently long to allow
2 the formation of sufficient amount of fibrin deposition on the device.

1 253. The device of Claim 244 wherein the delay is sufficiently long to allow
2 the formation of sufficient amount of fibrin deposition at the susceptible tissue site and on the
3 device.

1 254. The device of Claim 244 wherein the source comprises a rate-
2 controlling element disposed adjacent the expandable structure.

1 255. The device of Claim 244 wherein the rate-controlling element forms a
2 matrix with the therapeutic capable agent.

1 256. The device of Claim 244 wherein the rate-controlling element forms a
2 matrix with the therapeutic capable agent.

1 257. A kit for providing a therapeutic capable agent to a susceptible tissue
2 site including:

3 a device according to any one of Claims 74, 150, 238, or 241; and
4 a second compound.

1 258. The kit of Claim 257 wherein second compound is selected from the
2 group consisting of compounds according to any of Claims 151, 157, 162, 163, 164; and
3 combinations thereof.

1 259. The kit of Claim 257 wherein the second compound is an antiemetics
2 or an antinauseants.

260. The kit of Claim 259 wherein anti-nausea compound is selected from the group consisting of ondansetron such as Zofran™, dronabinol such as Marinol™, ganisetron.Hcl such as Kytril™, and combinations thereof.

261. The kit of Claim 257 wherein the second compound is another therapeutic capable agent according to Claim 151 or 157.

262. The kit of Claim 257 wherein the second therapeutic capable agent is the same as the therapeutic capable agent of the device.

263. The kit of Claim 257, 259, 261, or 262 wherein the second compound is administerable to a patient having the susceptible tissue site orally, pulmonarily, systemically, transdermally, through any bodily orifices, or any combinations thereof.

264. The kit of Claim 263 wherein the second compound is administerable to the patient prior to, concurrent with, or subsequent to an interventional procedure.

265. The kit of Claim 263 wherein the second compound is provided in a dosage ranging from about 0.5 mg to about 5g.

266. The kit of Claim 264 wherein the second compound is administerable to the patient in a time period from about 200 days to about 200 days after the interventional procedure.

267. The kit of Claim 264 wherein the second compound is administerable to the patient in a time period from about 30 days to about 30 days after the interventional procedure.

268. The kit of Claim 264 wherein the second compound is administerable to the patient in a time period from about 1 day to about 30 days after the interventional procedure.

269. The kit of Claim 264 wherein the second compound is administerable to the patient in a time period from about 200 days to about up to the interventional procedure.

1 270. The kit of Claim 264 wherein the second compound is administerable
2 to the patient in a time period from about 3 months to about up to the interventional
3 procedure.

1 271. The kit of Claim 264 wherein the bioactive compound is
2 administerable to the patient in a time period from about 7 days to about 24 hours prior to an
3 interventional procedure.

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